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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,659	08/20/2003	Eric Olson	MYOG:037US	6211

7590 05/20/2004

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EXAMINER

MONDESI, ROBERT B

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 05/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/644,659	OLSON ET AL.	
	Examiner	Art Unit	
	Robert B Mondesi	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-105 is/are pending in the application.
- 4a) Of the above claim(s) 18-23,35-60 and 71-105 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17,34 and 61-69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>20040502</u> . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election of Invention I, Claims 1-17, 24-34 and 61-69 (claim 70 is in Group VI drawn to non-human transgenic animals, classified in class 800, subclass 8) in response to election of restrictions, filed April 26, 2004 is acknowledged. Because applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). In a telephonic interview, on May 3, 2004 the applicants made a further election of SEQ ID NO: 1. **Claims 1-105** are pending. **Claims 18-23, 35-60, 71-105** are withdrawn by the Examiner for being drawn to non-elected subject matter. **Claims 1-17, 24-34 and 61-69** are currently under examination.

Priority

The current application filed on August 20, 2003 claims priority to provisional application 60/404,706 filed on August 20, 2002.

Information Disclosure Statement

The IDS filed October 27, 2003 has been received and is signed and considered; a copy of the IDS is attached to the following document.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In **claim 1** "STARS" needs to be spelled out in the first instance of use. **Claims 2-17** are dependent claims that do not further clarify the independent base claim.

In **claim 5**, "CMV", "MKC" and "HSV" need to be spelled out in first instance of use.

In **claims 7-17**, the phrase "complement thereof" is indefinite even though in the specification on page the applicants attempt to define the said phrase. The applicant defines "complement thereof" to be any sequence that hybridizes under stringent conditions with nucleic acid sequence represented by SEQ ID NO:1. The applicant is reminded that the "phrase stringent conditions" itself is indefinite and needs to be further defined. With regard to **claims 7-17**, directed to a polynucleotide sequence that hybridizes under stringent conditions to SEQ ID NO: 1, applicants have not sufficiently described the meaning of the term "stringent". Nucleic acid hybridization assays are extremely sensitive to the conditions in which they are performed. The buffer composition, pH, temperature, length of time, salt concentrations, quality and source of template nucleic acid, are all variables which determine the reproducibility of a given hybridization experiment. Given the unpredictability of the art and the nature of hybridization experiments in general, it is not sufficient to cite a laboratory reference which contains many different hybridization conditions which may be construed as being "stringent". The definition of "stringency" as it pertains to hybridization conditions is subject to interpretation and is different from laboratory to laboratory. Therefore, without a clear and explicit recitation of what conditions are meant to be included by the term "stringent", and without a clear and explicit recitation of the conditions which were

actually used by applicants in isolating polynucleotides which hybridize to SEQ ID NO: 1, the skilled artisan would not be able to practice the claimed invention and would not be reasonably apprised of the metes and bounds of the claimed invention. Without such guidance, the experimentation left to those skilled in the art is undue. Including in the claims the exact nature of the hybridization conditions used to isolate the claimed polynucleotides would aid in overcoming this portion of the rejection.

In **claim 17** the applicant states that nucleic acid of claim 7, comprises 2000 contiguous base pairs of SEQ ID NO:1. This is not possible because SEQ ID NO:1 is only 1146 base pairs long.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 7-14 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The nucleic acid as claimed, has a nucleic acid sequence duplicative of that of the nucleic acid molecule designated by SEQ ID NO:1 or the cellular precursor thereof and possesses the biological and functional properties of the naturally occurring nucleic acid molecule that encodes the STARS polypeptide and therefore does not constitute patentable subject matter absent recitation of "isolated and purified" in the preamble. See *American Wood v. Fiber Disintegrating Co.*, 90 U. S. 566 (1974); *American Fruit Growers v. Brogdex Co.*, 283 U. S. 1 (1931); *Funk Brothers*

Seed Co. v. Kalo Inoculant, 33 U. S. 127 (1948); and *Diamond v. Chakrabarty*, 206 USPQ 193 (1980).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 24-34 and 61-69 are rejected under 35 U.S.C. 102(b) as being anticipated by Arai et al.. Arai et al. disclose an expression construct comprising an isolated polynucleotide that encodes a STARS polypeptide, further comprising a CMV promoter (Materials and Methods, STARS Expression Plasmids, page 24454, column 1) wherein the polynucleotide is 100% similar to nucleic acid designated by SEQ ID NO: 1 (FIG.1, page 24455) (**present claims 1-6 and 24-34**). Arai et al. also teach a method of producing a STARS polypeptide in a cell, wherein said cell is a cardiomyocyte and is located in an animal. Arai et al. further teach that the transforming step of the above method comprises infection with a viral vector involving contacting of the mentioned cell with a liposome comprising an expression cassette and that the resultant STARS polypeptide is purified away from its cellular components (Materials and Methods, STARS Expression Plasmids, Transient Transfections, Reporter Assay, GST-STARS Purification, page 24454, columns 1-2) (**present claims 61-69**). Thus Arai et al. teach all the elements of **claims 61-69** and these claims are anticipated under 35 USC 102(b).

Claims 7-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Arai et al. (NCBI Sequence Submission, Accession Number AF503617). Arai et al. disclose a nucleic acid molecule comprising 1000 contiguous base pairs of nucleic acid molecule designated by SEQ ID NO:1 (NCBI Sequence Submission, Accession Number AF503617) (**present claims 7-16**). Thus Arai et al. teach all the elements of **claims 7-16** and these claims are anticipated under 35 USC 102(b).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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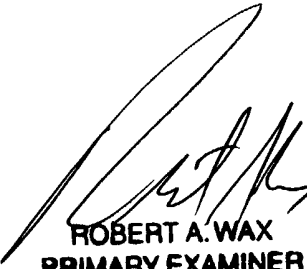
RB Mondesi

Robert B Mondesi

Patent Examiner

Group 1653

05-13-04


ROBERT A. WAX
PRIMARY EXAMINER